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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,224	07/01/2003	Phillip R. Cunningham	WSV-2597	5754

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EXAMINER	
AKHAVAN, RAMIN	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5/02/05 RA

Office Action Summary	Application No.	Applicant(s)	
	10/612,224	CUNNINGHAM, PHILLIP R.	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-26 and 29-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of a response, filed 02/09/2005, to a restriction requirement. Claims 1-36 are pending in this application.

Election/Restrictions

Applicant's election without traverse of Group II (claims 27 and 28) in the reply filed on 02/09/2005 is acknowledged. Therefore, claims 1-26 and 29-36 are withdrawn as drawn to nonelected subject matter. Furthermore, it is noted that Applicant elects SEQ ID NOs: 52 and 53 from the species defined by claims 4-6 and 15-17. However, since claims 4-6 and 15-17 are in a nonelected group, election of SEQ ID NO: 52 and 53 is not required for examination of the elected group, i.e., claims 27 and 28. Applicant is invited to contact the examiner if further clarification is required on this issue. Claims 27 and 28 are under consideration in this action.

Claim Objections

Claims 27 and 28 are objected to because of the following informalities: each of the claims is dependent from nonelected claims (claims 1 and 14 respectively). Claims 27 and 28 can technically be withdrawn from consideration for this reason since the limitations recited in the nonelected claims have been withdrawn from consideration. However, in the interest of advancing prosecution the claims are examined herein as though the explicitly recite the subject matter recited in the nonelected claims. The claims must be amended to incorporate the limitations for "the plasmid" so as to obviate improper dependence on nonelected claims.

In addition, the definite article "the" should be inserted before the term "functional" in claim 27, part *j*.

In claim 28, part *f* should define the corresponding terms for the acronym "GFP". Appropriate correction of the foregoing objections is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. **Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 27 and 28 are examined as though the claims explicitly recite the subject matter of claims 1 and 14 respectively. The terms "steps" and "parts" are used interchangeably with respect to the claims.

Claims 27 and 28 recite the limitation "the rRNA". The claims are vague and indefinite, because the limitation "the rRNA" lacks sufficient antecedent support. The base claims recite the term "rRNA gene" not "rRNA" and the two terms have distinct meaning (e.g., nucleic acid versus protein).

In part *c* of claims 27 and 28, the phrase "the regions of interest" lacks sufficient antecedent support. Further, in part *i* the phrase "the functional mutant ribosomes" lacks sufficient antecedent support.

With respect to part *h* of claim 28, it is unclear to which "selectable marker" the claim is referring.

In addition, the claims are ambiguous because the base claims recite that the rRNA gene has "a mutant Anti-Shine-Dalgarno sequence, at least one mutation in said rRNA gene". More particularly, it is unclear whether the claims are directed to two different mutations or that the mutation in the Anti-Shine-Dalgarno (ASD) sequence *is* the mutation in the rRNA gene. The former interpretation results in a completely different outcome, i.e., a mutation in the ASD, as well as at least a mutation elsewhere in the rRNA gene. The specification merely repeats the same language that is used in the claims. (e.g., p. 21, ll. 20-22). Applicant should clarify distinctly and particularly what is intended.

In addition, the claims are ambiguous because it is not clear how steps *b* to *f* relate to a method of identifying a drug candidate. More particularly, step *a* recites that a host cell is transformed with a plasmid that contains a mutually compatible ASD and Shine-Dalgarno (SD) pair, each respectively in a rRNA gene and a gene encoding selectable marker. However, steps *e* to *i* appear to be directed to reconstructing the very plasmid of base claims 1 and 14 and again transforming a host cell prior to steps which are directed to screening a drug candidate (i.e., *h* to *m*). Put another way, steps *e* to *i* do not relate with the preamble or with the additional positive action steps recite in the claims. The steps (*e* to *i*) appear to be directed to constructing the plasmids to which base claims 1 and 14 are directed, the very plasmids introduced into cell in step *a*. As written the claims are confusing and vague.

The source of the confusion appears to be that the claims incorporate method steps that are related to selection of a functional mutant ribosome-marker combination (i.e., steps *a* to *d*; e.g., Specification, p. 12, ll. 15-35; p. 20, Example 1).

Subsequent steps appear to be directed to further mutation of said selected functional mutants to optimize the specificity of the system (i.e., steps *e* to *i*). (e.g., p. 22, ll. 7-10). The ambiguity is further exacerbated by the fact that step *c* is not directed to identifying *functional* mutants, contrary to what is in the specification. (p. 21, l. 25). Therefore, method steps directed to optimizing a functional mutant (steps *e* to *i*) are not interrelated to what is claimed in the preamble (i.e., identifying a drug candidate). For example, a drug can be screened against the mutated ASD/SD pair that comprises a functional mutant selected in step *d*. Because of the discord between the preamble and the body of the claim, one of skill would not readily define the boundaries for the invention.

In addition, step *f* in claims 27 and 28 is ambiguous, because it is unclear how the step is to be interpreted. The step is directed to inserting mutated regions of interest into a plasmid that itself contains mutant ASD and a selectable marker with a compatible mutant SD sequence. First it is unclear to what the region of interest relates, because step *c* merely recites "to identify the regions of interest" without any notion as to what is the region of interest. Second, if the region of interest were interpreted to mean the mutant ASD sequence comprised in the plasmid of the base claims (claims 1 and 14), then its unclear how the resulting plasmid in step *f* can have two mutant ASD sequence. Furthermore, this embodiment does not appear to be contemplated in the specification.

In sum, in view of the foregoing ambiguities the claims are vague and indefinite, making indeterminable the claims' metes and bounds.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached between 8:30-5:00, Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD, can be reached on 571-272-0781. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636

GERRY LEFFERS
PRIMARY EXAMINER